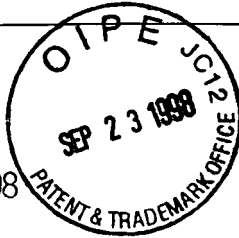




DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

SEP 18 1998



Re: Differin Solution (5,212,303)

Docket No. 96E-0353

RECEIVED

SEP 29 1998

PATENT EXTENSION  
A/C PATENTS

#14

Stephen G. Kunin  
Deputy Assistant Commissioner for  
Patent Policy and Projects  
Office of the Assistant Commissioner for Patents  
U.S. Patent and Trademark Office  
Crystal Park Building 2, Suite 919  
Washington, DC 20231

Dear Mr. Kunin:

This is in regard to the patent term extension application for U.S. Patent No. 5,212,303 filed by Centre International de Recherches Dermatologiques ("CIRD") under 35 U.S.C. § 156. The patent claims the human drug product Differin Solution (5,212,303) (adapalene), New Drug Application NDA 20-338.

In the January 2, 1997, issue of the Federal Register (62 Fed. Reg. 101), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before July 1, 1997, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs

cc: Norman H. Stepno  
Burns, Doane, Swecker & Mathis, L.L.P.  
P.O. Box 1404  
Alexandria, VA 22313-1404

ASSISTANT TO ASSISTANT  
FOR PATENTS

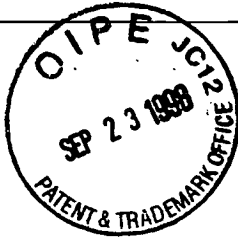
08 SEP 23 11 29 50



DEPARTMENT OF HEALTH & HUMAN SERVICES

9200

SEP 18 1998



Food and Drug Administration  
Rockville MD 20857

Re: Differin Topical Gel (5,212,303)  
Docket No. 96E-0355

Stephen G. Kunin  
Deputy Assistant Commissioner for  
Patent Policy and Projects  
Office of the Assistant Commissioner for Patents  
U.S. Patent and Trademark Office  
Crystal Park Building 2, Suite 919  
Washington, DC 20231

RECEIVED  
SEP 29 1998  
PATENT EXTENSION  
A/C PATENTS

#14

Dear Mr. Kunin:

This is in regard to the patent term extension application for U.S. Patent No. 5,212,303 filed by Centre International de Recherches Dermatologiques ("CIRD") under 35 U.S.C. § 156. The patent claims the human drug product Differin Topical Gel (5,212,303) (adapalene), New Drug Application NDA 20-380.

In the January 28, 1997, issue of the Federal Register (62 Fed. Reg. 4064), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before July 28, 1997, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs

ASSISTANT COMMISSIONER  
FOR PATENTS

98 SEP 29 PM 2:50

cc: Norman H. Stepno  
Burns, Doane, Swecker & Mathis, L.L.P.  
P.O. Box 1404  
Alexandria, VA 22313-1404



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

Re: Differin Topical Gel (5,212,303)  
Docket No. 96E-0355

Stephen G. Kunin  
Deputy Assistant Commissioner for  
Patent Policy and Projects  
Office of the Assistant Commissioner for Patents  
U.S. Patent and Trademark Office  
Crystal Park Building 2, Suite 919  
Washington, DC 20231

RECEIVED  
SEP 22 1998  
PATENT EXTENSION  
A/C PATENTS

Dear Mr. Kunin:

This is in regard to the patent term extension application for U.S. Patent No. 5,212,303 filed by Centre International de Recherches Dermatologiques ("CIRD") under 35 U.S.C. § 156. The patent claims the human drug product Differin Topical Gel (5,212,303) (adapalene), New Drug Application NDA 20-380.

In the January 28, 1997, issue of the Federal Register (62 Fed. Reg. 4064), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before July 28, 1997, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs

98 SEP 22 11 11 AM  
ASIS FOR PATENTS

cc: Norman H. Stepno  
Burns, Doane, Swecker & Mathis, L.L.P.  
P.O. Box 1404  
Alexandria, VA 22313-1404

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service  
Food and Drug Administration

**Memorandum**

Date:

From: **Brian J. Malkin, Associate Director for Patents and Hearings**  
**Health Assessment Policy Staff (HFY-20)**

Subject: **Patent Term Restoration Application**  
**for Differin Topical Gel (5,212,303)**

To: **Dockets Management (HFA-305)**

Attached is a letter to the Patent Term Office for the above mentioned drug under the Docket Number **96E-0355** stating that this particular patent is eligible for regulatory review. The Patent Number is **5,212,303**. Please place this recent correspondence in the appropriate file.

If you have any questions, please contact me at 827-6620. Thank you for your assistance.

98 SEP 22 AM 11:00  
ASSIS. IN. OF. PATENTS  
FOR PATENTS